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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,596	03/18/2004	Michael Lange	905.020US2	9548

21186 7590 08/23/2004

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

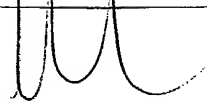
CHANG, CHING

ART UNIT PAPER NUMBER

3748

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/804,596	Applicant(s) LANGE ET AL. 
	Examiner Ching Chang	Art Unit 3748

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/18/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1(a). *Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Lange et al. (U.S. Patent 6,712,789).*

Although the claims are not identical, they are not patentably distinct from each other because the claim of the instant application are substantially the same as that claimed in the US '789 Patent; however, the scope of claim 1 in the instant application lacking the limitations of separable to the sheath, the sheath including at least one tab extending away from a longitudinal axis of the sheath, and sliding to a movable valve assembly, is broader than that of the claim 1 in US '789 Patent.

1(b). Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of Lange et al. (U.S. Patent 6,712,789).

Although the claims are not identical, they are not patentably distinct from each other because the claim of the instant application are substantially the same as that claimed in the US '789 Patent; however, the scope of claim 1 in the instant application lacking the limitations of separable to the sheath, a membrane, and sliding to a movable valve assembly, is broader than that of the claim 12 in US '789 Patent.

1(c). Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of Kraus (U.S. Patent 6,641,564).

Although the claims are not identical, they are not patentably distinct from each other because the claim of the instant application are substantially the same as that claimed in the US '564 Patent; however, the scope of claim 2 in the instant application lacking the limitations of the sheath including at least one tab extending away from a longitudinal axis of the sheath, a needle disposed within the dilator, a needle retraction mechanism coupled with the needle and the dilator, and sliding to a movable valve assembly, is broader than that of the claim 15 in US '564 Patent.

Claim Objections

2. Claims 10-16, and 17-22 are objected to because of the following informalities:

- " the longitudinal axis " after " along " , " the introducer " after " a portion of " ,
and " the movable longitudinal axis " after " aligned with " in claim 10 appear to
be – the movable valve longitudinal axis --, -- the introducing apparatus --, and –
the movable valve longitudinal axis --, respectively.
- " the coupling " after " the sheath with " in claim 17 appears to be -- a coupling --

Appropriate corrections are required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. ***Claims 1, 9, and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al. (US Patent 5,755,693).***

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Walker discloses an introducing apparatus (10) comprising: a tubular sheath (18) having an external diameter, the sheath having a sheath passage (24) including an internal diameter sized to receive a medical instrument (12) therethrough, the sheath extending from a sheath distal end to a sheath proximal end; a movable valve assembly (64, 64a) including a valve, the movable valve assembly movably coupled proximal to the sheath, the movable valve assembly movable from a first position (See Figs. 12 and 15) to a second position (other than the first position shown in Figs. 12 and 15) along a portion (28) of the introducing apparatus, in the first position the valve is disposed through the longitudinal axis of the sheath, in the second position the valve is disposed away from the longitudinal axis of the sheath, the movable valve assembly movable from the second position to the first position along the introducing apparatus while the medical instrument is disposed (See Fig. 15) through the sheath passage along at least the sheath proximal end; the movable valve defined in part by a movable valve longitudinal axis (perpendicular to the longitudinal axis of the sheath), the movable valve moves from a second position to a first position along the movable valve longitudinal axis; wherein the movable valve assembly having an open end (76) substantially aligned with the movable valve longitudinal axis, the open end traveling over at least a portion of the sheath passage when the movable valve assembly moves from the second position to the first position, and the valve disposed within at least a portion of the open end; wherein the valve comprises a membrane (30F), wherein the membrane has a slit (74) therein, wherein the slit is substantially parallel with the movable valve longitudinal axis, wherein the at least one tab (56, 58) is defined in part by a tab

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longitudinal axis, wherein the movable valve assembly includes a valve support member (70, 68, 66) coupled with a seal (30F), and the valve support member includes at least one arm (66, 68) at least partially encompassing the at least one tab.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. ***Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of Pohndorf et al. (US Patent 5,441,504).***

Walker discloses the invention, however, fails to disclose a dilator being used.

The patent to Pohndorf on the other hand, teaches that it is conventional in the art of a splittable lead introducer, to utilize a dilator (66) with an introducer (60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the dilator as taught by Pohndorf in the Walker device, since the use thereof would provide an alternative usage for an introducer.

7. ***Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of West (US Patent 6,322,541).***

Walker discloses the invention, however, fails to disclose a side port assembly being coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a side port assembly (19, 20) having a snap-fit or thread-connection to an introducer sheath (12).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the side port assembly as taught by West in the Walker device, since the use thereof would provide an improved introducer.

8. *Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US Patent 5,755,693) in view of West et al. (US Patent No. 6,322,541).*

Walker discloses an introducing apparatus comprising: an elongate tubular sheath (18) having an external diameter, the sheath having a bore (24) including an internal diameter sized to receive a cannula (12; or the like) therethrough, the sheath comprising a separable sheath (through 56, 58, and 18); the sheath extending from a distal end to a proximal end; the sheath including at least one tab (56, 58) extending away from a longitudinal axis of the sheath; and a movable valve assembly (64, 64a) movably coupled relative to the at least one tab, the moveable valve assembly adapted to move from a first position (See Fig. 12 and 15) to a second position (other than the first position, along 28), in the first position the movable valve assembly disposed through the longitudinal axis of the sheath, in the second position the movable valve assembly disposed away from the longitudinal axis of the sheath.

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Walker discloses the invention, however, fails to disclose a side port assembly being coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a side port assembly (19, 20), snap-fitted or thread-connected to an introducer sheath (12) having a dilator (14) therethrough.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the side port assembly as taught by West in the Walker device, since the use thereof would provide an improved introducer.

9. *Claims 2-7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claims 1 and 16 above) in view of Pohndorf et al. (US Patent 5,441,504).*

Walker discloses the invention, however, fails to disclose the movable valve assembly being slidable along the tab longitudinal axis.

The patent to Pohndorf on the other hand, teaches that it is conventional in the art of a splittable lead introducer, to utilize an introducer (60) with a dilator (66) therethrough and have a movable valve assembly (70) slidable along a tab longitudinal axis (72, 78).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the movable valve assembly with the slidable mechanism as taught by Pohndorf in the Walker device, since the use thereof would provide an improved introducer.

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10. ***Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Pohndorf et al. (as applied to claim 1), and further in view of West et a. (US Patent 6,322,541).***

The modified Walker device discloses the invention, however, fails to disclose a releasable side port being used.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a releasable side port assembly (19, 20) being used with a vascular introducer (10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the releasable side port as taught by West in the modified Walker device, since the use thereof would provide an improved introducer.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Honerbrink et al. (US Patent 6,589,262).

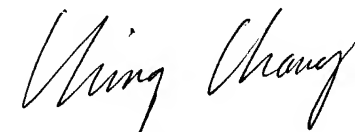
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ching Chang whose telephone number is (703)306-3478. The examiner can normally be reached on M-Th, 7:00 AM -5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Denion can be reached on (703)308-2623. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent Examiner



Ching Chang



THOMAS DENION
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700